Remarks/Arguments:

I. Introduction

Upon entry of the present amendment, claims 1-12 will be pending in this application. Claim 1 has been amended to clarify that the active agent is an antigen, that the immune response generated is in response to the antigen, and that the calcium phosphate portion of the composition is a nanoparticle. Claim 12 has been added to define a particle for use in the claimed method. Upon receiving a notice of allowance, Applicants will cancel the withdrawn claims. Based on the following remarks, Applicants respectfully request reconsideration and allowance of the pending claims.

II. 35 U.S.C. §112

A. Immunity

The Examiner has rejected claims 5-7 under 35 U.S.C. 112, second paragraph, as being indefinite. The Examiner's position is that the phrase "induce immunity in a patient" is still unclear. The Examiner does not understand what immunological responses are encompassed by the term, even after Applicants have pointed to clear and specific instances in the specification where the term is unambiguously defined and specific examples are set forth. The Examiner asks to what, if anything, the immune response is directed and whether the immune response is directed to the calcium phosphate particle or the "pharmacologically active agent." He has also asked whether the immune response is specific or non-specific.

Applicants have amended claim 1 to clarify that the immune response in generated in response to the antigen that is associated with the calcium phosphate nanoparticle.

Applicants continue to submit, however, that the particular immune response will depend upon the antigen to be delivered and that the specification provides *numerous* examples of potential responses. As the Examiner knows, "[t]he presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure." MPEP 2164.02.

B. Substantially spherical and substantially smooth

The Examiner has also rejected claim 5 as vague and indefinite due to the terms "substantially spherical shape" and "substantially smooth surface." The Examiner's position is that it is unclear what degree of smoothness or roundness is engendered by the term "substantial." Although Applicants have argued this point at length in previous responses, the patentability of the invention does not rely on these features, and accordingly, the terms have been removed from the claims.

III. Double Patenting

The Examiner has issued a provisional double patenting rejection over claims 5-7 over claims 10-12 of co-pending Application No. 10/824,097. Without acquiescing to the Examiner's rejection, in the interest of advancing the prosecution of this application, Applicants will file a terminal disclaimer upon the allowance of the pending claims.

IV. 35 USC § 102

Claims 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Nuwayser (U.S. Patent 5,648,097). The Examiner's position is that the pending claims are drawn to methods of inducing immunity in a patient using substantially smooth and substantially

round calcium phosphate particles with a diameter ranging from 300 nm to 4000 nm at least partially coated and or impregnated with an antigen. The Examiner states that the Nuwayser patent discloses methods for adsorbing biologically active compounds to calcium phosphate particles wherein the resulting particles serve as controlled release drug delivery vehicles (see abstract, column 5 lines 16-36); that the Nuwayser particles are substantially spherical and substantially smooth (see column 3, lines 52-54); and that the biologically active agent or drug can include multitude of compounds including antigens and vaccines. The Examiner believes that Nuwayser contemplates application to mucosal surfaces because some of the disclosed "biologically active agents" include antihistamines and decongestants (see column 6, lines 13-18). Applicants respectfully traverse the Examiner's rejection and request reconsideration and withdrawal thereof.

Nuwayser is not relevant to the claimed invention for at least two reasons: (1) its particles are much larger than the particles of the claimed invention and (2) its particles are not delivered to a mucosal surface, but are instead injected into the patient.

A. Particle Size

First, Nuwayser is not relevant to the present invention because the calcium phosphate particles of the instant invention are much smaller than the microparticles disclosed in Nuwayser. Applicants have amended claim 1 to recite that the calcium phosphate particle(s) is/are "*nanoparticles*," in contrast to the *microparticles* of Nuwayser, which "range in size from one micron to several millimeters in diameter." *See* Nuwayser, col. 2, lines 13-15. (This amendment does not necessarily mean that the *resulting particle*

that is delivered is a nanoparticle because the antigen may be coated on the outside of the nanoparticle, causing the final particle to be slightly larger.)

B. Injection vs. Delivery to Mucosal Surface

Moreover, the microparticles of Nuwayser are intended to be injected or implanted. *See* Nuwayser col. 3, lines 18-21 and lines 65-67, col. 4, lines 6- 7 and lines 38-41. There is no teaching or suggestion that the large particles of Nuwayser would succeed in the delivery of drugs across the ocular surface, as Applicants claim. The Examiner's position is that because antihistamines and decongestants are among a long list of active agents that can be delivered using the Nuwayser microparticles, the Nuwayser reference contemplates mucosal use of its particles. That is incorrect. There are plenty of instances when antihistamines and decongestants are delivered via injection, via a syrup or pill that is intended to act through the alimentary tract, and so forth. Accordingly, the disclosure of delivering antihistamines and decongestants does *not* mean that mucosal delivery is implied by the Nuwayser reference. Quite the contrary – every discussion of delivery of the Nuwayser particles relates to injection.

Accordingly, because (1) the Nuwayser particles are not nanoparticles (before being combined with drugs) and because (2) the Nuwayser particles are injected and not applied to an ocular surface, Applicants respectfully request that the rejections be withdrawn.

CONCLUSION

For at least the above reasons, Applicant respectfully requests allowance of claims 5-7 and 12 and issuance of a patent containing these claims in due course. If there remain any additional issues to be addressed, the Examiner is urged to contact the undersigned attorney at 404.815.6147.

Respectfully submitted,

Kristin Crall

Kristin M. Crall
Reg. No. 46,895

KILPATRICK STOCKTON LLP
1100 Peachtree Street
Suite 2800
Atlanta, Georgia, 30309-4530
404.815.6147